

Application No. 10/068,812  
Amendment and Response  
Response to Office action dated June 18, 2003

Docket No.: 034298-122

### RESPONSE

Claims 1-16 are pending in the present application. Claims 1-16 have been rejected. Claims 9 and 12 have been amended to correct spelling errors. New claim 17 has been added and is supported in the specification on page 11, lines 9-13. No new matter has been added.

#### Claim Rejections – 35 USC §112

Claims 2, 3, 6, 7, and 15 were rejected under 35 USC §112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter.

Specifically, claims 2 and 3 “recite the limitation ‘foaming’ in claim 1. There is insufficient antecedent basis for this limitation in claim 1.” Claims 2 and 3 have been amended to recite the following:

2. (currently amended) The hemostatic cross-linked gelatin composition of Claim 1, wherein the wetting agent is impregnated with the gelatin prior to ~~foaming a~~ foaming process of the gelatin.
3. (currently amended) The hemostatic cross-linked gelatin composition of Claim 1, wherein the wetting agent is mixed with the gelatin prior to ~~foaming a~~ foaming process of the gelatin.

It is respectfully asserted that there is now sufficient antecedent basis for the limitation and request that this rejection be withdrawn.

Claims 6 and 7 “recite the limitation ‘foaming’ in claim 5. There is insufficient antecedent basis for this limitation in claim 5.” Claims 6 and 7 have been amended to depend from new claim 17 that recites the following:

17. (new) The method of claim 5 further comprising foaming said cross-linked gelatin.

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It is respectfully asserted that there is now sufficient antecedent basis for the limitation and request that this rejection be withdrawn.

Claim 15 "recites the limitation 'the sponge' in claim 1. There is insufficient antecedent basis for this limitation in claim 1." Claim 15 has been amended to provide for antecedent basis by amending "the sponge" to "the gelatin".

It is respectfully asserted that there is now sufficient antecedent basis for the limitation and request that this rejection be withdrawn.

#### **Claim Rejections – 35 USC §102**

Claims 1-6, 8-13, and 15 are rejected under 35 U.S.C. 102(e) as being allegedly anticipated by US PGPB 2002/0042378 (the '378 application). This rejection is respectfully traversed.

According to the M.P.E.P., a claim is anticipated under 35 U.S.C. § 102(a), (b) and (e) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.<sup>1</sup>

The office action states:

"The present claim 1 recites composition comprising cross-linked gelatin and wetting agent. The claim recites the amount of wetting agent intended to permit wetting of gelatin in the presence of an aqueous solution. . . . claim 5 recites method for decreasing the hydration time of cross-linked gelatin composition comprises incorporating wetting agent with the gelatin prior to its hydration. . . .

<sup>1</sup> Manual of Patent Examining Procedure (MPEP) § 2131. See also *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

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PGPB '378 disclosed hemoactive material or composition that is suitable for inhibiting bleeding, i.e. hemostatic, and are delivered to the target region in the tissue subject to bleeding (page 2: 0012; page 5:0039). The material comprises cross-linked biologically compatible polymer, non cross-linked biologically compatible polymer, and plasticizer (abstract; page 2:0016). The most preferred cross-linked polymer is gelatin (page 3:0031; page 5: example 2). The non cross-linked polymers include cellulose derivatives, polyvinyl polymers, and polyoxyethylenes; and the plasticizers include polyethylene glycol and sorbitol (page 2: 0016, 0018), all disclosed by applicant in the first full paragraph of page 9 of the instant specification as wetting agents. . . . Decreasing the hydration time of the cross-linked gelatin that [is] claimed in claim 5 is inherent in the material of the reference that comprises cross-linked gelatin and polyethylene glycol, and that has the wetting agent incorporated with the cross-linked gelatin prior to use and hydration."

The Examiner equates the wetting agent of the present invention to the non cross-linked polymer of the '378 application. The Examiner also claims that decreasing the hydration time of the cross-linked gelatin is inherent in the material of the reference that . . . has the wetting agent incorporated with the cross-linked gelatin. Applicant respectfully disagrees.

Claims 1 and 5 provide for:

1. A biocompatible, hemostatic, cross-linked gelatin composition comprising a cross-linked gelatin and a sufficient amount of wetting agent to permit uniform wetting of the gelatin in the presence of an aqueous solution.
5. A method for decreasing the hydration time of a hemostatic cross linked gelatin composition which method comprises, prior to hydration of said cross-linked gelatin composition, incorporating a biocompatible wetting agent with said cross-linked gelatin.

The wetting agent of the present invention is incorporated into the gelatin to permit uniform wetting of the sponge in the presence of an aqueous solution to decrease the hydration time of the gelatin composition. (Specification, page 7, lines 20-23). The wetting agent, as defined in the specification, is to facilitate or enhance the hydration of a hemostatic sponge. (Specification 9, lines 3-4).

The '378 application specifically states that the "non-cross-linked polymer is chosen to solubilize relatively rapidly when exposed to blood. The non-cross-linked polymer serves as a

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binder for holding the materials in desired geometries, such as sheets, pellets, plus, or the like" (Abstract). As stated in the '378 application, the sheet of hemoactive material "immediately begins absorbing water from the blood present at the site. Within minutes, the non-cross-linked polymer component of the material will begin to dissolve and release the cross-linked particles." (page 5: 0040). Thus, the non-cross-linked polymer is to merely bind the cross-linked particles in a desired shape and to quickly dissolve, by absorbing water from the blood, so that the cross-linked particles can form a hydrogel.

The '378 application does not suggest or teach a non-cross-linked polymer that provides for uniform wetting of the cross-linked gelatin nor does the '378 application suggest or teach a non-cross-linked polymer that enhances the hydration time of the cross-linked polymer as claimed in claims 1 and 5. The '378 application teaches a non-cross-linked polymer that merely solubilizes rapidly to expose the cross-linked polymer. Thus, the non-cross-linked polymer of the '378 application does not promote uniform wetting or enhance hydration time of the cross-linked polymer as claimed in claims 1 and 5.

The Examiner states that decreasing the hydration time of the cross-linked gelatin is inherent in the material of the reference that comprises cross-linked gelatin and polyethylene glycol, and that has the wetting agent incorporated with the cross-linked gelatin prior to use and hydration. However, arguments based on inherent properties cannot stand when there is no supporting teaching in the prior art references.<sup>2</sup> The '378 application merely teaches the absorption of the non-cross-linked polymer to expose the cross-linked polymer, and not to decrease the hydration time of the cross-linked polymer itself. Moreover, the '378 application does not teach incorporating the non-cross-linked polymer with the cross-linked gelatin as claimed in claim 5. Thus, it cannot be said that decreasing the hydrating time of the cross-linked gelatin is inherent when a wetting agent is incorporated with the cross-linked gelatin.

Thus, since each and every element as set forth in claims 1 and 5 are not found, either expressly or inherently described, in the '378 application, it can not be said to anticipate the present invention. Thus, it is respectfully requested that this rejection be withdrawn.

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<sup>2</sup> *In re Spormann*, 363 F.2d 444, 150 USPQ 449 (CCPA 1966).

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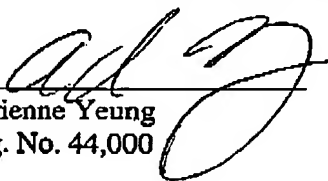
**Request for Allowance**

It is believed that this Response places the above-identified patent application into condition for allowance. Early favorable consideration of this application is earnestly solicited.

If, in the opinion of the Examiner, an interview would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney at the number indicated below.

Respectfully submitted,  
THELEN REID & PRIEST, LLP

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